DIAGNOSTIC VALIDITY OF ORTHOPANTOMOGRAPH COMPARED TO DEXA SCAN IN SCREENING OSTEOPOROSIS IN GERIATRIC POPULATION

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LIST OF ABBREVIATIONS USED

BMD	**BONE MINERAL DENSITY**
DEXA	**DUAL ENERGY X-RAY ABSORPTIOMETRY**
DXA	**DUAL ENERGY X-RAY ABSORPTIOMETRY**
CB	**CORTICAL BONE**
TB	**TRABECULAR BONE**
MCI	**MANDIBULAR CORTICAL INDEX**
OP	**OSTEOPOROSIS**
OPG	**ORTHOPANTOMOGRAM**
MIC	**MANDIBULAR INFERIOR CORTEX**

LIST OF PHOTOGRAPHS

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ABSTRACT

BACKGROUND: Osteoporosis is a condition characterized by a loss on bone mineral density and there is micro- architectural deterioration in bone tissue leading to fracture. Dental radiographs are the most frequently used imaging modalities for teeth and jaw pathology.

AIM: The aim of this study were to review the role of panoramic radiograph in routine dental treatment for an initial evaluation of osteoporosis and to discuss the reliability and accuracy of reported panoramic indices.

METHODOLOGY: We present to the dental society the Klemetti index(Mandibular cortical index- MCI). In this technique the inferior cortex both sides of the mandible, distal to the foramen mentale, is classified into three groups, according to the mandibular bone thickness, shape and porosity.

C1- normal cortex- the endosteal margin of the cortex is even and sharp on both sides.

C2- mildly to moderately eroded cortex, the endosteal margin has resorptive cavities with cortical residues one to three layers thick on one or both sides.

C3- Severely eroded cortex, the cortical layer forms endosteal cortical residues and is clearly porous.

Patients having positive findings related to MCI should be evaluated further for potential risk of osteoporosis and were referred to a medical specialist for densitometry.

RESULTS: Based on the OPG findings bone, the sample was classified into C1 (n=20), C2 (n=20) and C3 (n=20) groups. Statistically significant differences were found for mean Mental index (p=0.000), mean Panoramic Mandibular Index (p=0.001). The sensitivity (100%) and specificity (88.88%) of MCI showed good results.

CONCLUSION: In conclusion, valuation of mandibular cortical index(thickness and shape of inferior cortex of mandible), measuredfrom panoramic radiography was a simple technique inosteoporosis screeming of dental patients, giving themaximum benefit of being radiographed.

Key words: Mandibular, Klemetti index, Mandibularcortical index- MCI, Panoramic radiography, Osteoporosis, Dental treatment.

INTRODUCTION

The significance of prevention and early detection is not only in conditions which are irreversible but also in conditions which are hard to treat once they advance. Such a condition is osteoporosis. Osteoporosis is characterized by decrease in Bone Mineral Density (BMD) and thus an increase in risk of fracture[1]. An overall reduction in bone mass that is less severe than osteoporosis, caused by the resorption of bone at a frequency exceeding bone synthesis is called osteopenia[1]. It causes fragility fractures on minimal injury where otherwise normally a micro-fracture will not occur. The vertebral column, hip and wrist being the most common sites of such fractures[2]. Patients may complain of non-specific musculoskeletal and bone pains, numbness, decrease in height and even deformity[3].

In both men and women the maximal bone density is attained by 30 years, after which peak bone mass decelerate which is more pronounced in females post menopause. Osteoporosis is the most common metabolic bone disorder in the adults, especially in postmenopausal women. Osteoporosis is most commonly seen in females of old age as a result of lack of estrogen, labeled as menopausal osteoporosis[4]. As the life expectancy is increasing the number of cases of osteoporosis are also expected to rise. Increase in the number of reproductive years is protective against osteoporosis because of estrogen. Without estrogen, osteoclasts becomes more active leading to increased bone destruction. During the first 5 years of the postmenopausal period, bone mass can be reduced by 20% (approximately 2%– 3% of trabecular bone [TB] and 1%–2% of cortical bone [CB]. Due to the difference in the distribution of TB and CB, different remodeling takes place in different bones at different time. The areas with a higher amount of TB (e.g., spine, hip, calcaneus) are more susceptible to the development of osteoporotic processes,

but bone changes and reduction also occur in those skeletal bones where the content of CB is high, e.g., in the mandible.

The diagnosis of osteoporosis is based on the physical signs and symptoms, x-rays, bone scans and bone mineral density (BMD) assessment. According to World Health Organization T-score of -2.5 or below is defined as osteoporotic, T-score of -1.0 or greater is normal and T-score between -1.0 and -2.5 is osteopenia. The gold standard for determining osteoporosis is DEXA (Dual Energy X-ray Absorptiometry)[6].

Different techniques are used for the assessment of bone mineral density. Worth mentioning are single or dual energy X-ray absorptiometry (SXA- DXA), single or dual photon absorptiometry (SPA-DPA), Quantitative Computerized Tomography (QCT), and Quantitative Ultrasound (QUS) which are expensive and may not be available at places[10].

The diagnosis of most of the osteoporosis in second world nation as India, where bone densitometry is not in reach of all common men due to its high cost and unavailability of this equipment at many diagnostic center limits its usefulness for screening examination, is done when they come to the emergency with fracture femur neck.. OPG are mainly done for evaluation of dental examination, dental pain to detect and scrutinize dental diseases and conditions as it is very cost effective as compared to the other advanced imaging modalities. The use of these radiographs for assessing individuals with low skeletal bone mineral density would be very economical and beneficial as the dentists can refer the patient for further examination if required due to its availability and simplicity. These X-rays could easily be used for early detection of osteoporosis if dental and orthopedic community goes hand in hand. Dental panoramic radiographs are used in different studies to observe mandibular cortical changes. Thin

cortical width has been observed in low bone mineral density subjects. Mandibular Cortical Index (MCI) for diagnosing osteoporosis in postmenopausal women. Recent studies show statistically significant results in values of MCI on panoramic radiographs according to gender and dental status[8].

Unavailability of solid epidemiological data regarding the prevalence of osteoporotic incidence and fractures in developing second world nation as India is the major hindrance in planning programs for osteoporosis.

Indeed some investigators[10] demonstrated the significant association between skeletal BMD and jawbone or periodontal condition, other studies[11] failed to find this association. The results of these studies should be interpreted with caution, since the age of the subjects might not have been restricted, and oral and skeletal bone loss might have been measured only in women. Further studies are needed in both men and women restricted by age in south Indian population . Till date no studies have been carried out in this field in geriatric population of south India to evaluate osteoporotic state assessment with OPG using cortical integrity. The purpose of this study was to establish an association between morphological changes in the cortex of mandible on OPG and DXA scan of right and neck femoral neck and spine to see whether or not the OPG X-ray can be employed for early detection of bone density reduction related to osteoporosis in geriatric population of south India.

AIMS AND OBJECTIVES

Aim of the study is to evaluate the efficacy of OPG as a diagnostic tool in detecting osteoporosis/osteopenia suspected changes in jaw and confirming the finding with DEXA scan in south Indian geriatric population using mandibular cortical index (MCI).

The objective of the study is to

1. Obtain complete history and Clinically evaluate patients with sign and symptoms of osteoporosis in geriatric population.
2. Radiographic evaluation using orthopantomogram to detect osteoporotic changes in mandibular cortex.
3. Effectiveness of orthopantomograph using mandibular cortical index in diagnosing osteoporosis and comparing the findings with DEXA scan

Osteoporosis is a disease characterized by low bone mass and the development of nontraumatic or atraumatic fractures as a direct result of the low bone mass. A nontraumatic fracture has been arbitrarily defined as one occurring from trauma equal to or less than that of a fall from a standing height. In the preclinical state the disease is characterized simply by low bone mass without fractures. This totally asymptomatic state is often termed "osteopenia:' Osteoporosis and osteopenia are the most common metabolic bone diseases in the developed countries of the world, whereas osteomalacia may be more prevalent in underdeveloped countries where nutrition is suboptimal and vitamin D deficiency common[12]. And this has become a serious debilitating condition in case of elderly especially females who are more prone to bone loss after their menopause due to hormonal imbalance and other co-factors.

The contribution of oral bone loss to the overall morbidity in the aging population cannot be underestimated, and the amount of alveolar bone loss after tooth extraction may also limit the overall retention and stability of dentures. This fact alone increases the difficulty in the construction of the prosthesis. For many years the gradual resorption of the alveolar bone was thought to be due only to local factors such as the loss of the functional influence of the teeth on the surrounding tissues, direct loading of the alveolus by complete dentures, continuous wearing of ill-fitting dentures, and periodontal disease. Currently the literature suggests a relationship between systemic bone loss from osteoporosis and the resorption of the edentulous alveolar ridge.

Definition:

In 1993, osteoporosis was defined as a "disease characterized by low bone mass and microarchitectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk". A more recent definition from the National Institutes of Health Consensus Development Panel on Osteoporosis defines osteoporosis as a skeletal disorder characterized by compromised bone strength predisposing a person to an increased risk of fracture. Clinically, bone strength is estimated by non-invasive assessment of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA). Numerous epidemiologic studies confirm that low BMD is among the strongest risk factors for fracture. As endorsed by the World Health Organization (WHO), the clinical diagnosis of osteoporosis is based on BMD measurements and the presence of fractures. For these diagnostic criteria, BMD is transformed into a T-score, which reflects the number of standard deviations (SD) above or below the mean in healthy young adults.

The World Health Organization (WHO) convened an expert panel to define osteoporosis on the basis of bone mass measurement[13]. The diagnostic categories that were established by that panel are as follows[12]:

- Normal: bone mineral density or bone mineral content less than 1 SD of the young adult reference mean

- Low bone mass: bone mineral density or bone mineral content between (osteopenia) -1.0 and -2.5 SD lower than the young adult reference mean

- Osteoporosis: bone mineral density or bone mineral content more than -2.5 SD below the young adult reference mean

- Severe (established): osteoporosis with one or more osteoporosis fragility fractures Osteoporotic fractures may affect any part of the skeleton except the skull. Most commonly, fractures occur in the distal forearm (Colles' fracture), thoracic and lumbar vertebrae, and proximal femur (hip fracture).

EPIDEMIOLOGY

With propelling age, BMD reduces and prevalence of osteoporosis increases. In the United States, Europe and Japan, osteoporosis affects around 75 million individuals[14]. Utilizing the WHO criteria, 30% of postmenopausal Caucasian women have osteoporosis at the hip, lumbar spine or distal lower arm[15]. This is equivalent with the danger of fracture for a 50 year old women at any one of these places. By the age of 80 years, 70% of women are osteoporotic at the hip, lumbar spine or distal lower arm[15]; in 2002, there were 8 million osteoporotic women and 2 million osteoporotic men in the US. The prevalence of osteoporosis, evaluated utilizing the reference values among the young population, differs by location. In Sweden 6.3 % of men and 21.2 % of women between 50 to 80 were diagnosed osteoporotic, while among people between 80 to 84 years, 16.6 % of men and 47.2 % of women were osteoporotic.

Osteoporosis causes around 9 million fractures every year around the world, of which more than 4.5 million happen in the Americas and Europe. The assessed lifetime hazard for a wrist, hip or vertebral fracture is around 30 to 40% in first world nations, close to that for coronary artery illness. Subsequently, at the age of 50, a Caucasian women evaluated for a lifetime risk of an osteoporotic fracture is 46-53%. In comparing, the evaluated lifetime fracture hazard for Caucasian men is 13 to 21%. The assessed lifetime danger of hip fracture in 50-year old Caucasians ranges from 17% to 23% in women, and from 6% and 11% in men. The danger of clinical vertebral break is marginally lower at age 50, with a lifetime danger of 15% in ladies and 8% in men. The lifetime risk of occurrence of radiographic vertebral fracture in ladies is substantially higher ~27% and comparative in men, 11%[16].

The risk of contacting an osteoporotic fracture escalates exponentially with age because of the reduction in BMD and the presence of other age-related variables, e.g. increased frequency of falls. In this manner, rising the average life expectancy results in an growing number of osteoporotic fractures. In addition, age-adjusted rate of fragility fracture have expanded in the course of the most recent three decades of the twentieth century, partly, we believe its due to a more inactive way of life

Interestingly, the pattern for increased age-related rate of fragility fractures has changed throughout in the recent 10 years. In spite of the fact that the age-specific rate of osteoporotic fractures (essentially hip fractures) keeps on expanding in a few nations[17], in other nations, it has leveled off or even decreased[18]. Several variables contribute to this phenomenon. As life expectancy increases, at a given age an individual might be more healthier. Higher rate of obesity and lower tobacco smoking enhance the maintenance of bone mass and more use of anti-osteoporotic treatment may likewise diminish the incidence of osteoporotic fracture.

This current decrease in age-adjusted frequency of fracture has just been observed in Western population, and the effect of these positive patterns on the number of the fragility fracture worldwide is limited. Consequently, the increase in the number of osteoporotic fracture (mostly hip fracture) can be anticipated in Middle East, Asia, and Latin America, where the life expectancy is expected to rise in the coming decades. It is assessed that, in these areas, the aggregate number of hip fracture will multiply more than fivefold between 1990 and 2050. Men suffer 20 to 30% of all osteoporotic fracture and this is presumed to rise. Likewise, it is assessed that in 2025, the number of hip fractures happening worldwide in men will be much the same as in 1990 women. Same way, men may succumb to other general patterns which may impart influence on the fracture risk (growing life expectancy, inactive lifestyle), osteoporosis in elderly

men keeps on being underestimated, understudied, and underdiagnosed and treated. Therefore, societal liability of osteoporosis in elderly men keeps on expanding.

Osteoporotic fractures are a serious public health issue worldwide because of the related morbidity, mortality and costs. The financial hardship of osteoporotic fractures comprises direct costs (medical centre acute care, in-hospital rehabilitation, outpatient assistance, prolonged nursing care) and indirect costs (morbidity, working days lost). Some costs are hard to quantify, e.g. retrogression of quality of life, and time invested by the family on the wellbeing of the patient. Treatment of associated conditions following a fracture comprises 75% of the comprehensive healthcare cost of osteoporotic fractures. Non-spine non-hip osteoporotic fractures are also liable for a significant percentage of the worldwide health and financial burden of osteoporosis, predominantly in people between 50 to 65 years, when these fractures are 10 to 20% more common than hip fractures[51,52]. Non-spine-non-hip fractures lead to hospital admission, disability, worsening of quality of life and working days lost. Overall, osteoporosis is a major public health problem and its social significance will rise further with the estimated increase in the quantity of osteoporotic fractures and their economic and human costs.

Importantly, the financial cost of osteoporotic fractures is high and is increasing rapidly. In the USA, the estimated direct cost of osteoporosis is 19 billion in the US in 2005 and expected to increase by 50% by 2025. Every year in the USA, 3.5 million hospital bed days are attributed to osteoporotic fractures and over 60,000 nursing home admissions are attributed to hip fractures. Trends are similar in Europe, where the estimated cost of osteoporotic fractures was 36 billion euro in 2000 and is expected to double to 77 billion euro by 2050 [22,23].

In conclusion, in all countries, osteoporotic fractures are expensive and their costs are projected to increase on a per-fracture basis and also because the total number of fractures is projected to rise. However, the net financial burden depends on the healthcare level and economic status of the country. Thus, the higher number of fragility fractures due to the increasing life expectancy in developing countries as India may constitute a serious challenge for their economies during the coming decades.

PATHOGENESIS OF OSTEOPOROSIS AND RISK FACTORS FOR FRACTURE

Age-specific changes in BMD

Bone mass and BMD increase rapidly during childhood and adolescence, key times for longitudinal and radial skeletal growth. During this time, increase in areal BMD (g/cm2) is largely related to the increase of bone size. In boys, longitudinal growth lasts for a longer period of time than in girls, both before and during puberty. Therefore, men are taller than women. Radial growth in boys also lasts for a longer period of time than in girls. Therefore, men have wider bones than women even after adjustment for height and length of body segments[24]. As areal BMD depends partly on bone size, men have higher BMD when measured by dual-energy X-ray absorptiometry (DXA). After growth stops, consolidation is the final phase of the formation of peak BMD. Subsequently, two processes determine changes in BMD: periosteal apposition and bone loss which involves trabecular bone and the endosteal surface of the cortical bone. In young adults, these processes are in equilibrium and areal BMD is stable. When bone loss outweighs periosteal bone gain, BMD begins to decrease.

Age-related bone loss is greater in women than in men. During the first years after the menopause, there is rapid bone loss, largely in the trabecular compartment, that leads to trabecular perforation followed by loss of entire trabeculae. When the trabeculae disappear, the metabolically active surface available for bone resorption decreases and trabecular bone loss slows down. Cortical bone loss also accelerates with age and consists of cortical thinning and increasing cortical porosity. By the age of 80, the amount of trabecular and cortical bone lost is around 40 % from the premenopausal peak BMD.

In men, slow bone loss starts soon after attainment of peak BMD then accelerates exponentially after the age of 70. In men, trabecular bone loss consists mainly of trabecular thinning which compromises bone strength less than the loss of entire trabeculae. The mechanism of cortical bone loss is similar in both sexes but of smaller magnitude in men. The lifetime bone loss in both compartments in men is about 20 to 25 %. Thus, in men, peak BMD is higher and bones are larger, whereas aging-related bone loss is of smaller magnitude and structurally less detrimental to bone strength in comparison with women. Therefore, the age-specific incidence of osteoporotic fractures is lower in men than in women.

Hormonal disturbances:

The hormonal changes occurring at menopause are a major factor leading to osteoporosis in women. An abrupt reduction in ovarian function results in a rapid decrease in 17β-estradiol secretion which leads to an increased secretion of cytokines that activate osteoclasts, including RANKL, interleukin-1β, interleukin-6 and tumor necrosis factor α. The resulting increase in bone resorption leads to bone loss and microarchitectural deterioration, as described above.

In men, gonadal function decreases slowly. Even in older men, the average concentration of total testosterone is only 20 % lower than in young men and, in many elderly men, the total testosterone level remains in the normal range. By contrast, concentrations of bioavailable and free testosterone are 50-60 % lower than those found in young men. However, the main sex steroid regulating bone turnover in older men is 17β-estradiol, especially its bioavailable fraction[25] Men with the lowest bioavailable 17β-estradiol levels have lower BMD, higher levels of biochemical bone turnover markers (BTM), accelerated bone loss, a higher prevalence of vertebral fractures and higher incidence of hip fracture [25,26].

Secondary hyperparathyroidism due to vitamin D and calcium deficit also contributes to bone loss in elderly men and women. Intestinal calcium absorption decreases with age. Decreased synthesis of endogenous vitamin D results from aging of the skin and from lower sunlight exposure. Decreased synthesis of 1α,25-dihydroxycholecalciferol [1α,25(OH)2D], the active form of vitamin D, results from the age-related reduction in the activity of renal enzyme 1α – hydroxylase. Decrease in 1α,25(OH)2D production contributes to the decrease in intestinal calcium absorption and circulating calcium levels[27]. Consequently, the secretion of parathyroid hormone (PTH) increases and PTH stimulates bone resorption, mainly in the cortical bone.

Other risk factors for osteoporosis and for osteoporotic fractures:

Many studies highlight the role of hereditary factors in the pathogenesis of osteoporosis. Epidemiological studies show a significant correlation of BMD in twins, the correlation being stronger in monozygotic than dizygotic twins. Furthermore, women whose mothers sustained a hip fracture have a lower BMD and a higher risk of fragility fracture compared to women whose mothers did not suffer a hip fracture. Indeed, twin and family studies suggest that up to 80% of the variability in peak bone mass is attributable to genetic factors[26]. Whereas a number of gene variants have been implicated in low BMD and increased fracture risk, genes responsible for the specific heritable component of osteoporosis have not been conclusively identified.

Lifestyle factors that increase the risk of low BMD and fractures include alcohol abuse, smoking, low calcium intake, and lack of physical activity. These factors are interrelated: smokers tend to drink more alcohol, often have a poorer diet and take less physical activity. They also tend to be thinner. Lifestyle factors also interact with other factors; for example, components of tobacco smoke influence enzymes involved in the metabolism of steroid hormones.

Some diseases also increase the risk of osteoporosis, including hyperthyroidism, Cushing's disease, haemochromatosis, primary biliary cirrhosis, hypogonadism, multiple myeloma, chronic obstructive pulmonary disease, beta-thalassaemia, and diseases of the digestive tract impairing intestinal absorption such as Crohn's disease, coeliac disease and chronic pancreatitis. Some drugs increase the risk of osteoporosis, e.g. glucocorticoids (especially long-term oral use), thyroid hormone excess (mainly suppressive treatment after thyroid cancer), anti-androgen treatment (gonadotrophin releasing hormone agonists, surgical castration), aromatase inhibitors, thiazolidinediones, loop diuretics, proton pump inhibitors, selective serotonin reuptake inhibitors (SSRIs) and some drugs used in the treatment of AIDS (mainly tenofovir, protease inhibitors).

Risk factors for fractures:

Epidemiologic studies have identified several factors that increase an individual's risk of fracture. While a thorough review is beyond the scope of this document, several key risk factors are highlighted. Among the strongest risk factors for fracture are low BMD, advanced age, female sex, Caucasian ancestry, and previous history of fracture. Specifically, the risk of fractures is markedly increased (two- to four-fold) in subjects with prevalent fragility fractures, regardless of age and BMD. In addition, factors that increase the likelihood of falling are associated with fractures. Hence the risk of fracture is higher in 72

patients with condition that increase the risk of falls (hemiplegia, frailty, lower limb dysfunction, Parkinson's disease, cardiovascular disorders leading to orthostatic hypotension) and among patients treated with neuroleptics, antidepressants and antihypertensive drugs. As noted in the following text, several diseases and medications can increase the risk of fractures[28].

CLASSIFICATION OF OSTEOPOROSIS

In addition to describing osteoporosis as being of the high- or low-turnover type, there are several other classification systems. The first is the classification into "primary" and "secondary:' the latter being osteoporosis for which a clearly identifiable etiological mechanism is recognized. Primary osteoporosis is further characterized into "postmenopausal" and "senile:' In "postmenopausal" osteoporosis there is an apparent excess loss of cancellous bone, with relative sparing of cortical bone, and the clinical syndromes involve Colles' fracture and vertebral fracture. In "senile" osteoporosis there is a more concordant loss of both cortical and cancellous bone. The pathogenesis of senile osteoporosis is uncertain, but it is postulated to result from an age-related decline in renal production of 1,25-dihydroxyvitamin D and calcium malabsorption, with subsequent secondary hyperparathyroidism. It is the hyperparathyroidism that is largely responsible for the excess cortical bone loss. Fracture syndrome often seen in the patient with senile osteoporosis characteristically involves the hip and pelvis.

Osteoporotic fractures – clinical manifestation of osteoporosis

Vertebral fractures

Vertebral fracture is the most common osteoporotic fracture. They may occur in the absence of trauma or after only minimal trauma, such as bending, lifting or turning. In individuals aged over 50 years, the prevalence of vertebral fracture is similar in men and women, largely due to increased presence of traumatic fractures in men that were incurred during their youth[29]. In a study performed in different European countries where all radiographs were analyzed in one reference centre, the prevalence of vertebral fractures varied from 10-24% according to the diagnostic criteria. Prospective epidemiological studies show that the incidence of new vertebral

fractures in elderly men is half that occurring in women of the same age[30]. Annually, one 65 year old woman among a sample of 100 and one man among a sample of 200 will sustain a new vertebral fracture. The incidence of vertebral fractures increases dramatically with age[31]. For instance, the risk of sustaining a new vertebral fracture is about two times higher at 75 years of age than at 65 years of age.

Vertebral fractures have a major personal and societal impact in terms of disutility and financial costs. The clinical symptoms of vertebral fractures are back pain, limitation of spine mobility, loss of height and disability[32]. They can be associated with difficulty in bending, rising, dressing, climbing stairs, as well as reduced pace of walking, reduced independence or even the need to use a walking aid[33]. Back pain and disability as well as difficulties in performing activities of daily living are observed mainly in patients with fractures in lower thoracic and lumbar spine, whereas fractures in the mid-thoracic spine can result in a mild reduction of pulmonary function[35].

Vertebral fractures result in a deterioration of the health-related quality of life mainly through back pain, reduced physical capability, perceived poor general health and emotional status (e.g. fear of falling, lack of independence, purposeful limitation of activity and of social interactions). Deterioration of quality of life is more pronounced in patients with several vertebral fractures. Incident vertebral fractures are associated with a marked deterioration in the quality of life and with an average bed rest ten times higher than in osteoporotic women without incident vertebral fracture.

The risk of vertebral fractures increases significantly with decreasing BMD, and these fractures are an important clinical manifestation of osteoporosis. A vertebral fracture (assessed using a

standard radiograph or Vertebral Fracture Assessment software) is an independent predictor of subsequent osteoporotic fractures, especially of the spine and hip**.** After adjustment for age and BMD, a prevalent vertebral fracture is associated with a four- to five-fold increased risk of suffering a subsequent vertebral fracture. The risk of a new vertebral fracture increases with both the number and the severity of prevalent vertebral fractures[36]. A fifth of osteoporotic women with a recent vertebral fracture will sustain a new vertebral fracture within the next 12 months, highlighting the need for prompt diagnosis and rapid, effective treatment.

In addition, epidemiological studies report a higher mortality in patients with osteoporotic vertebral fractures, with age-adjusted mortality rates increasing with the number of vertebral fractures[105]. For example, clinical vertebral fractures are associated with an 8-fold increase in age-adjusted mortality, which is similar to the increase in mortality seen following a hip fracture. The excess mortality in patients with vertebral fractures may, in part, be attributable to their poorer health status. The financial burden of vertebral osteoporosis and associated fractures is significant and, in the elderly, includes the costs of hospitalization and of subsequent rehabilitation[38]. In the working population, medical costs associated with vertebral fractures are related to outpatient care and to the loss of working days.

However, despite their major personal and societal impact, vertebral fractures often do not come to clinical attention. This is thought to be for two main reasons. Firstly, about two thirds of vertebral fractures do not give clinical symptoms and may be only detected on a radiograph. Clinical symptoms of vertebral fractures are not specific and may be confused with osteoarthritis and other causes of back pain. Secondly, even on spine radiographs, vertebral fractures are often undiagnosed. In a large population of osteoporotic women recruited into a therapeutic trial, vertebral fractures were not adequately reported in at least 30% of patients and this poor result

was obtained in reference centers focused on osteoporosis. The rate of under-diagnosis may be even higher in general clinical practice. Vertebral fractures are not appropriately reported in the radiology and medical records (and, consequently, in healthcare insurer databases)[39]. In elderly hospitalized patients who had a lateral chest radiograph, less than 50% of vertebral fractures identified later on X-rays were reported in the radiological reports and even fewer in the medical records[40].

Consequently, only about 40% of older women with vertebral fractures visible on X-ray are referred for DXA measurement of BMD and receive adequate anti-osteoporotic treatment[41]. It is even lower (less than 20%) for men.

Thus, the clinical importance of vertebral fractures can be summarized as follows:

1. Vertebral fractures are common in both women and men and their incidence increases with age.

2. Vertebral fractures increase the risk of new vertebral fracture four to five-fold and the risk of other fragility fractures two- to four-fold.

3. Vertebral fractures are associated with an increased mortality.

4. Vertebral fractures lead to chronic pain, kyphosis, height loss, disability, and reduced quality of life.

5. The presence of a low trauma vertebral fracture is a clear indication of the need for treatment for osteoporosis, independent of BMD and of other risk factors.

Hip fractures

Hip fracture is one of the most disastrous consequences of osteoporosis. Its incidence increases exponentially with age in men and women[42]. The two main determinants of the risk of hip fracture are low BMD and increased risk of falls[42,43]. Many risk factors for hip fracture act through these two determinants. Low BMD is attributable to increasing age, low body mass index (BMI), weight loss after the age of 25 years, lack of physical activity, poor nutrition, tobacco smoking, chronic alcoholism, gastrectomy, certain diseases, and some medications (mainly glucocorticoids, loop diuretics and thyroid hormones). The risk of hip fracture is also increased in people with prevalent fractures, mainly vertebral and distal radius fractures, regardless of BMD[44].

The risk of falls also increases with age, especially in the frail elderly with compromised neuromuscular function, poor physical performance, visual impairment, or insulin-treated diabetes[45]. The impact of the fall depends on its direction (falls sideways on the hip are more likely to lead to fracture) and on the thickness of tissues surrounding the upper part of femur[46]. Aging is associated both with a decrease in BMD and with an increased risk of falls. Poor nutrition, vitamin D and calcium deficit as well as protein deficiency are common in the elderly and contribute to bone loss and to a loss of fat and muscular tissue which results in a higher risk of falls and poor protective mechanisms.

Mortality is increased 15 to 25% in the year following hip fracture, with particularly high rates in men. Hip fractures frequently result in a temporary or permanent loss of independence, institutionalization and permanent deterioration of quality of life. A substantial number of people with hip fracture experience a second hip fracture which is characterized by higher mortality than the first fracture. The cost of hip fracture is high and includes hospitalization, surgical treatment and rehabilitation as well as the costs of outpatient care, particularly institutionalization.

Non-hip-non-spine fractures

Fracture of the distal radius is one of the most frequent osteoporotic fractures in women and one of the earliest manifestations of osteoporosis. Its incidence increases in the early postmenopausal years and then stabilises[47]. In men, the incidence of distal radius fractures increases with age only slightly and remains low throughout life. In elderly men, the incidence is four times lower compared with women of the same age. In postmenopausal women, risk factors for this fracture are advancing age, an early menopause, low BMD, low BMI, falls (mainly falling forward on the hand), prevalent fragility fractures, height loss (often due to vertebral fractures), and a history of parental osteoporotic fractures.

Fracture of the distal radius rarely requires hospitalization. However, it is associated with a temporary decrease in independence, deterioration in quality of life and, in working people, loss of working days. Sudeck's atrophy is a common complication of fracture of the distal forearm. While this fracture is often considered a minor fracture, people who have sustained this fracture have a two to three times higher risk of other osteoporotic fractures, mainly of the hip, pelvis, vertebrae and humerus. Therefore, it should be regarded as the first signal of osteoporosis necessitating full diagnostic assessment.

Fracture of the proximal humerus is common in osteoporotic patients. After 50 years of age, its incidence increases with age in both men and women[48]. However, at any given age, its incidence is two to three times higher in women compared with men. Similar to other fragility fractures, the two main risk factors for fracture of the proximal humerus are low BMD, mainly at the distal forearm, increased risk of falls and prevalent fragility fractures[49]. Proximal humerus fracture results in a temporary loss of independence, deterioration in the quality of life, increased risk of

hip fracture and increased mortality. Other common sites for fragility fractures are the ribs, pelvis, clavicle, femur and tibia. These fractures are important for two principal reasons. Firstly, they may be the first manifestation of osteoporosis and associated increased bone fragility. Secondly, they may have important personal and societal consequences[50].

DIAGNOSTIC PROCEDURES

Dual-energy X-ray absorptiometry (DXA):

Evaluation of BMD by DXA is based on measuring the differential tissue-dependent (bone vs soft tissues) absorption of energy from two photon beams of different energy obtained using an X-ray source[50]. DXA is used to measure BMD at the lumbar spine, hip, distal forearm, calcaneum and whole body. It measures areal BMD, expressed in g/cm2, which depends on the volumetric BMD (vBMD, expressed in g/cm3) and on bone size. Thus, areal BMD does not distinguish if higher BMD relates to a higher amount of bone mineral or simply bigger bones. However, fracture risk is determined by the degree of bone mineralization and by bone size. Therefore, a greater areal BMD is significantly associated with a reduced risk of fracture, even after adjustment for confounding factors.

Stability, accuracy (trueness) and reproducibility (precision) are principal parameters of reliability of DXA measurements. Stability of the DXA device should be confirmed by daily measurement using a spine phantom. Accuracy is important for the screening of patients and for assessment of fracture risk. DXA is reliable in diagnosing osteoporosis and evaluating fracture risk. Although there is a normal biological variability of BMD at various skeletal sites, values of BMD at different sites of measurement are strongly correlated in an individual. Thus, measurement of BMD at two skeletal sites provides a good evaluation of the bone status and of the general fracture risk. However, the best predictor of the risk of fracture at a given site is BMD measured at this site. Hence hip fracture risk is best predicted by hip BMD, whereas vertebral fracture risk is best predicted by spine BMD.

Reproducibility is important mainly in the prospective evaluation of bone loss and of the effect of anti-osteoporotic treatment. As precision error (1-2 %) is high compared with the rate of bone loss or bone gain during anti-osteoporotic therapy, a minimum interval of two years between measurements is necessary for monitoring therapeutic efficacy. The accuracy and the reproducibility of the BMD measurement depends on two components: stability of the DXA device on one hand and, on the other hand, correctness and consistency of the positioning of the patient.

The **lumbar spine** is a common site for assessment by bone densitometry. However, presence of osteoarthritis results in a false increase in BMD in the elderly, especially in men. The presence of scoliosis or of lumbar vertebral fractures may give rise to inaccurate measurement of the spine BMD. Correct identification of lumbar vertebrae L1 to L4 is necessary to provide a correct assessment of the spine BMD. Therefore, it is important that the scan window is sufficient to visualise the iliac bone and lowest ribs which are helpful as landmarks for the identification of vertebrae. Measurement of lateral BMD eliminates the posterior arch with its processes and has been suggested as a method to partially reduce the effect of osteoarthritis on BMD in the lumbar spine; however, its accuracy error is high. Moreover, in some patients (especially in the elderly), upper lumbar vertebrae are partly covered by the lowest ribs, whereas L4 may be partly covered by the iliac crests, which renders this measurement unreliable.

The **total hip and its components** are a reliable site of measurement especially in elderly subjects who have a high risk of hip fracture and in people with severe lumbar osteoarthritis, scoliosis or fracture. The best sites are the femoral neck and total hip. Both predict fracture risk equally well. The total hip area is more suitable for monitoring treatment as it is a large area comprising cortical and trabecular bone. By contrast, BMD measurements in the trochanter and

Ward's are not useful in clinical practice. Appropriate positioning (slight internal rotation of the lower limbs) is particularly important to obtain reliable data. It should be also stressed that different manufacturers use different definitions of the region of interest (ROI) of the femoral neck and of the lower border of the total hip area.

Several devices measure BMD of the **distal forearm**. The most distal enlarged part of the radius is composed mainly of trabecular bone whereas the cortical envelope is thin (except subchondral cortical bone). The most proximal ROI measured, called the one-third-distal radius, is composed of about 95% cortical bone. The intermediate ROI is composed mainly of cortical bone and the trabecular fraction depends on the segment of the radius measured by a given type of DXA device. Different devices for evaluating distal forearm BMD use different algorithms to define the limits of the ROIs and measure slightly different parts of bone. Therefore, results obtained using different devices should not be compared.

Quantitative computed tomography (QCT):

In quantitative computed tomography (QCT), the X-ray source and detector rotate in a synchronized fashion around the subject as X-rays are passed through the body. Mathematical algorithms are then used to reconstruct the attenuation data into 3D images. Use of a bone mineral (or hydroxyapatite) phantom allows calibration of the image data, providing a measurement of bone density that unlike DXA is independent of bone size and can be obtained separately in the trabecular and cortical bone compartments. Advantages to QCT are that it can be employed on standard clinical scanners with relatively short imaging times, providing robust assessment of geometry and volumetric bone density in trabecular and cortical compartments at sites most prone to fracture, although the radiation exposure is a concern for some subjects.

Additional data are needed on the ability of QCT-based measures to predict fracture risk prospectively.

High resolution peripheral quantitative computed tomography (HR-pQCT):

Recently, a high-resolution, peripheral CT (HR-pQCT) system capable of achieving resolutions of up to 80 μm at tolerable radiation doses has been introduced for assessment of trabecular and cortical microarchitecture in the distal radius and distal tibia[164,168]. This technique has excellent precision for both density (<2%) and microstructure (<4%) measurements. Longitudinal HR-pQCT measurements indicate that whereas substantial cortical bone loss begins in middle life in women, it does not commence significantly until after age 75 in men. In contrast, trabecular bone loss begins early in adulthood in both women and men, such that approximately 40% of total life-time trabecular bone loss occurs before age 50, as compared to less than 15% for cortical bone. Altogether, HR-pQCT technique is highly promising for assessment of trabecular and cortical architecture in vivo and has high precision. However, it requires specialized scanners, and measurements are limited to peripheral skeletal sites.

Quantitative ultrasonography:

In quantitative ultrasonography (QUS), bone mass is assessed by two main parameters of ultrasound transmission: speed of sound (SOS) and broadband ultrasound attenuation (BUA)[57]. QUS equipment evaluates bone integrity at the calcaneus, phalanges of the fingers, patella and tibia[57]. The calcaneus should be very sensitive to disturbances of bone turnover because it contains 90 % trabecular bone which is metabolically very active. It has been claimed that QUS reflects not only bone quantity but also its trabecular microarchitecture and material properties of bone such as elasticity and stiffness. The degree of technical diversity of QUS devices is larger

than in DXA. This increases the difficulties in comparing measurements between different QUS devices and may lead to misinterpretation of results.

Despite several advantages (noninvasive, free of ionizing radiation, small inexpensive equipment which can be easily transported), QUS has not acquired a place in routine clinical practice. The long term stability of these devices is often poor. Values of QUS parameters measured *in vivo* depend on the temperature of the water bath and skin, positioning of the foot, the concentration and type of detergent and the soft tissue thickness. There are no QUS derived diagnostic thresholds of osteoporosis. Furthermore, it is not clear whether QUS could be helpful for the assessment of bone loss and for initiating anti-osteoporotic treatment. QUS should not be used for monitoring of anti-osteoporotic treatment. Quality control procedures and standardization of the regions of interest require further improvement.

Magnetic resonance imaging (MRI):

Magnetic resonance (MR) imaging offers a non-ionizing method to assess bone microarchitecture[58]. The most common MRI approach for bone quality assessment uses a strong magnetic field in combination with specialized sequences of radiofrequency pulses to generate 3D images of bone structure[58]. Because free hydrogen in water generally provides the 'signal' in this type of MR imaging and since the water content of bone is minimal, there is generally little signal provided by bone in standard MR imaging. As a result, bone structure is assessed indirectly via measurements of the surrounding marrow and other soft tissues. Advances in the past decade have focused on image acquisition and analysis techniques to overcome inherent obstacles in MR imaging of bone. It is not possible to produce accurate values for most features of trabecular architecture with MR resolution. Nonetheless, the "apparent" trabecular properties

that are derived from these images correlate strongly with measurements of trabecular architecture obtained with higher resolution.

MR-derived trabecular microarchitecture measurements have been shown to reflect age- and disease-specific difference[59,60], and to differentiate patients with hip and vertebral fractures from control subjects, with the best performance provided by combinations of structural parameters and BMD. There are no studies demonstrating prospective fracture risk prediction and limited data on treatment-related changes. Currently, MRI is only used in research studies and its application for the clinical management of osteoporosis is not yet established.

Biochemical markers of bone turnover:

Measurement of biochemical bone turnover markers (BTM) is a noninvasive method to evaluate bone metabolism. There are two groups of BTM. Biochemical markers of bone formation include serum concentrations of proteins secreted by active osteoblasts: osteocalcin, bone specific alkaline phosphatase (BAP), procollagen type I N-propeptide and C-propeptide[63]. Biochemical markers of bone resorption are mainly products of catabolism of resorbed type I collagen measured in serum and urine: C-terminal and N-terminal crosslinking telopeptides of type I collagen, deoxypyridinoline (crosslinking molecule) and certain amino acids such as hydroxyproline or galactosylhydroxylysine.

Role of orthopantomogram in detecting BMD changes:

Bone resorption occurs at the same time in the mandible than in the rest of the body; therefore, mandibular and spinal bone loss could be considered as manifestations of the same condition. Mandibular bone mass has been correlated with whole skeletal bone mass[64,65]. Evidence exists that osteoporosis influences the mandibular status, although the contribution of osteoporosis in the loss of mandibular cortical width (MCW), periodontal bone tissues, number of teeth and heights of the residual ridges has not been clearly assessed.

Osteoporosis affects the craniofacial and oral structures with the same rate as the total body and has been found to be connected with periodontal bone loss and tooth loss[66]. There is a positive correlation between the number of teeth and BMD at spine and hip[67]. Increased rates of BMD are associated with greater risk of tooth loss and the rate of edentulism among postmenopausal women with osteoporosis is approximately three times that of non-osteoporotic women[202].

The panoramic radiograph is a widely used imaging modality in dental practice. It is the second most frequently used diagnostic X-ray investigation used in general dental practice and perhaps the most frequent diagnostic X-rays in the oral and maxillofacial surgical practice.

Dental panoramic x-ray or orthopantomogram (OPG) is a routine examination in everyday dental practice. It is estimated that millions of patients undergo dental x-ray examination annually, whereas dental radiological examinations are among the most common reason for x-ray exposure. Several indices assessed in OPGs are used in the literature in order to correlate mandibular changes and BMD[69]. For most of them, the cortical margin of the lower jaw is used, as it is more obvious and easy to detect compared to the trabecular bone. Furthermore, the area below the mental foramina is mostly studied, due to (1) the usual lack of muscle attachment there

and (2) the fact that the distance between the mental foramen and the inferior margin of the mandibular cortical bone remains relatively stable during the lifespan, irrespective of the alveolar bone resorption following tooth extraction or inflammation.

One of the firstly described radiographic indices is the Mandibular Cortical Index (MCI), also referred to as the Klemetti index or Cortical Erosion which describes the porosity of the inferior border of the mandible and is related to the mandibular bone mineral density. This index involves measurements at the inferior mandibular cortex at the distal to the mental foramina part of the mandible, bilaterally, and findings are separated into three groups. In the first group (C1) the inferior mandibular cortical bone margins are even, while in the second group (C2) moderate erosion exists, as assessed by semilunar findings along the mandibular margin, and also by residues of the cortical bone one to three layers in thickness. The third group (C3) refers to cases with major erosion and cortical porosity. Klemetti et al studied 77 postmenopausal women and found that changes in the mandibular cortex, as shown in OPGs, are significantly related to buccal cortex BMD of lower jaw. These results are similar with the research by Cakur and others, who found that MCI is correlated to vertebral BMD

. It is clear that the dentist has a role in screening undetected osteoporosis in patients who seek dental care, without additional x-ray exposure or time consuming clinical examination, but only by performing the necessary tests for the dental treatment. The major contributor for the low BMD screening is the panoramic x-ray. However, frequently OPG x-rays are of low quality, due to the use of outdated x-ray equipment or the patient's malpositioning. In this case, they have low diagnostic value for diagnosing osteoporosis. Furthermore, in most studies with positive diagnostic results, dental radiology experts or dentists who underwent special training on the subject took part, but results varied greatly amongst untrained general dentists[70]. This can

partially be attributed to the variation in panoramic x-ray quality, the absence of illuminator and magnifying graticules in many instances, and most importantly by the dentists' ability to recognize the exact points of anatomical radiomorphometric indices.

MATERIALS AND METHODS

The study was conducted at Department of Oral Medicine and Radiology, Tamil Nadu Government Dental College and Hospital, Chennai – 600 003. The study protocol was approved by the Institutional Ethical Committee.

Duration of the study: From June 2016 to November 2017.

Sample design:

Totally 60 cases were included under the study out of which 25 were female and 35 were male. The cases were selected from the Department of Oral Medicine and Radiology, Tamil Nadu Government Dental College and Hospital, Chennai – 600 003 between June 2016 and November 2017. All were in the age group of 60 years and above.

Methodology:

A cross sectional study was conducted on out patients reporting to the Department of Oral Medicine and Radiology with dental complaints of the jaws with/ without associated pain were subjected to a thorough clinical examination, details of which were entered into the structured proforma specially made for the study. Wherever indicated, conventional radiographs, OPG was taken to arrive at a provisional diagnosis of reduced BMD.

An informed consent was obtained from all the patients those who have fulfilled the inclusion and exclusion criteria. The study protocol was approved by the Institutional Ethical Committee. OPG for each patient was taken in Department of Oral Medicine and Radiology, Tamil Nadu Government Dental College and Hospital, Chennai–600 003.

Inclusion criteria:

- Age : male and female >60
- Routine dental disorder advised for opg

Exclusion criteria:

The exclusion criteria were a medical history positive for:

- Metabolic bone disease (hyperparathyroidism, hyperthyroidism, osteomalacia, osteogenesis imperfecta, renal osteodystrophia, and Paget disease).
- Hormone therapy (estrogen or pharmaceutical supplements) or antiosteoporotic drugs, and other medications, such as corticosteroid drugs that influence the bone metabolism.
- Cancer with bone metastasis.
- Destructive lesions in the jaw bones (such as malignant tumors or osteomyelitis).
- Renal insufficiency or blood origin malignancies.
- Tobacco or alcohol consumption.

All the radiographs were analyzed by using the criteria proposed by Klemetti et al[3]. The visual analysis was done by radiographic appearance of the lower border of the mandible near the mental foramen of the left side in panoramic radiographs which is based on MCI. The MCI at lower border of mandible in panoramic radiograph is basically a three point index (C1-3) and was assessed using the following criteria.

- C1: the endosteal margin of the cortex was even and sharp on both sides (Fig I)
- C2: the endosteal margin showed semilunar defects (lacunar resorption) or seemed to form endosteal cortical residues (one to three layers) on one or both sides.(Fig II)

- C3: the cortical layer formed heavy endosteal cortical residues and was clearly porous.(Fig III)

These markers were selected on the basis of simplicity of technique, nonrequirement of special equipment or instruments for measurement, and less time consumption in their calculation compared to other morphometric and densitometric markers. And more importantly, this index uses those mandibular sites for assessments that are relatively resistant to resorption due to local factors such as periodontitis. As the inferior cortex of mandible are away from the alveolar bone and are a part of the basal bone, changes in this region is a consequence of general factors rather than local factors. The armamentarium required for assessment included an optimal dark room conditions for OPG assessment. Patients having positive findings related to MCI were evaluated with further investigations to confirm osteopenia and osteoporosis(DEXA scan).

After which the patients were referred for an DEXA center to get a confirmatory final diagnosis based on the T- score. Hip and lumbar spine (L1-L4) BMD was measured by using the DXA method with the Discovery DXA® densitometer device (Hologic Inc., Bedford, MA, USA). The BMD values were classified based on the T-score levels.

The interpretation of the score based on the WHO criteria for osteoporosis is:

1. T‑score of −1.0 and above was normal

2. T‑score of −2.5 and lower than a T‑score of −1.0 was osteopenic

3. T‑score of −2.5 and below was Osteoporotic.

The patients who were confirmed to have osteopenia, osteoporosis or even normal were recorded and results were compared with the OPG already taken.

The results were tabulated and analyzed to assess the relation between the MCI of panoramic radiograph and the bone mineral density obtained from DEXA of Hip and lumbar spine (L1-L4).

PHOTOGRAPHS

Figure 1: Armamentarium

Figure 2: OPG Machine (Model: ORTHOPHOX XG3: 64kVp; 8 mA; 14 sec)

Figure 3: DEXA Machine (Model: Hologic Discovery Wi; 140 kVp; 2.5 mA; 49 sec)

Figure 4: C1

Figure 5: C2

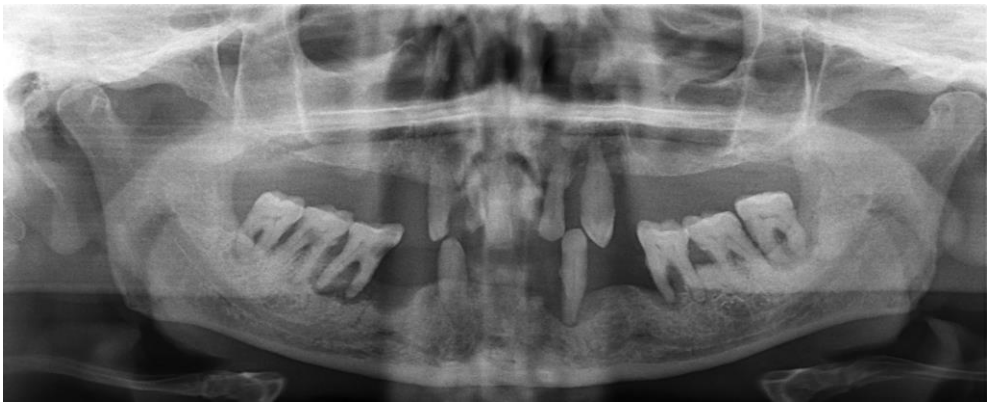


Figure 6: C3

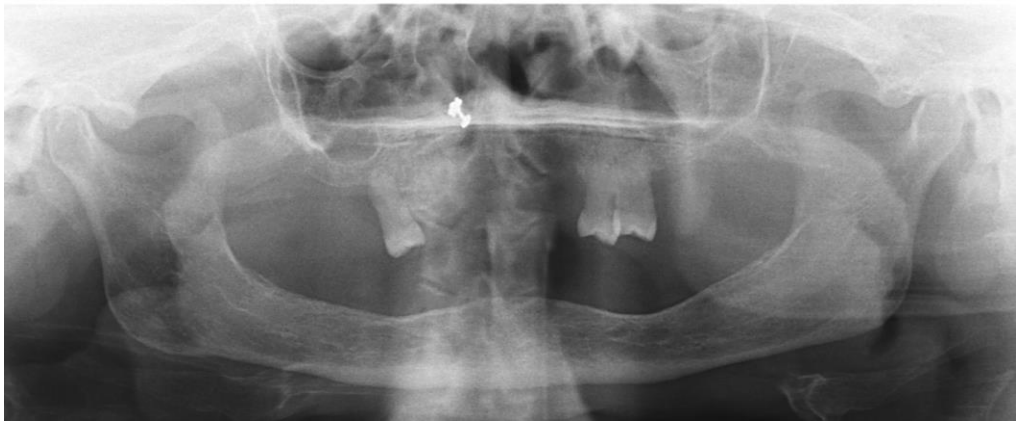
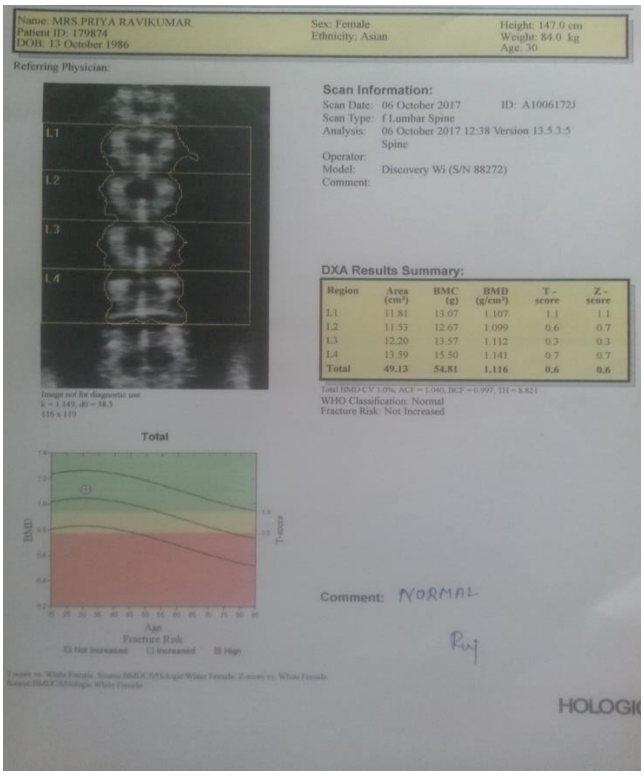
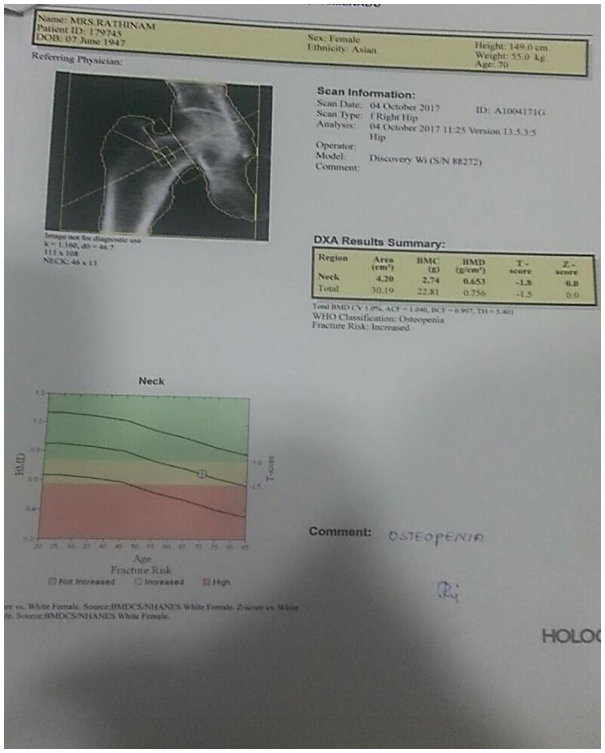
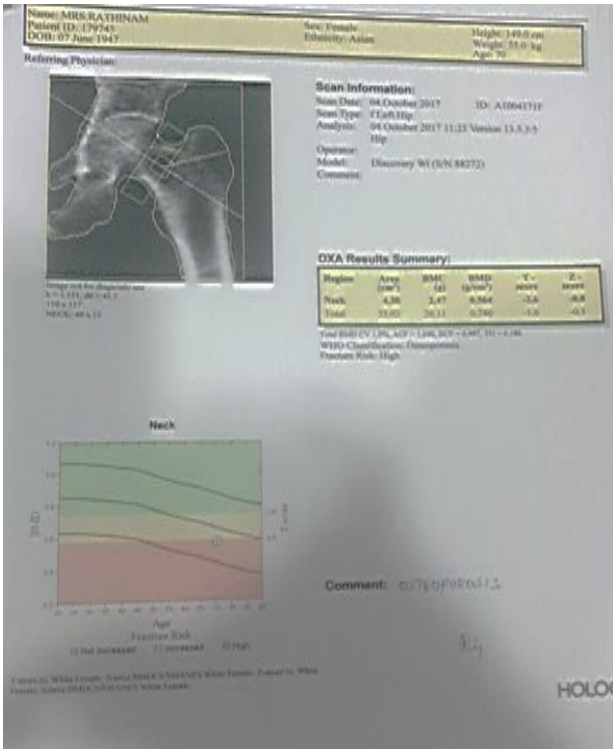


Figure 7: DEXA REPORTS







STATISTICAL ANALYSIS

Data was analysed using SPSS Version 23. Descriptives, frequencies and chi sq test were done to analyse the data

Formulation of Hypothesis:

Null Hypothesis: H_0 = There is difference in osteoporosis identification by DEXA and MCI index

Alternate Hypothesis H_a = There is no difference in osteoporosis identification by DEXA and MCI index

P value < 0.05 is considered as statistically significant.

If P value < 0.05 we can reject the null hypothesis and consider the alternate hypothesis

RESULTS AND OBSERVATION

This clinical study was conducted among the patients attending the Department of Oral Medicine and Radiology, Tamilnadu Government Dental College and Hospital. In the present study, totally 60 cases were included and were provisionally diagnosed using clinical examination, OPG as either as C1, C2 and C3 based on mandibular cortical index. Those patients suspected of reduced bone density were subjected to densitometric examination to establish the final diagnosis. Cases diagnosed were then tabulated and analyzed to assess the relation between the MCI of panoramic radiograph and the bone mineral density obtained from DEXA of Hip and lumbar spine (L1-L4).

Table 1 shows the distribution of study population according to gender. In C1 group, 75% were males and 25% were females where as in C2 group 40% were females and 60% were males and vice versa in C3 group. This clearly depicts that frequency of females increases as the mandibular cortex gets atrophic.

Table 2 reveals that the mean age of study population in C1 group is 62.20 while it is 65.50 and 64.40 in C2 and C3 respectively indicating the greater the age, greater is the susceptibility to osteopenia and osteoporosis. What we could infer from this is that as the mean age increases, susceptibility of mandibular cortex to get atrophic also increases which could be concluded by saying as the age increases, risk of developing reduced bone mineral density also increases.

Table 3 shows, Dexa reports showed 60% normal and 40% osteopenia in C2 group. Higher rates of osteopenia of 70% were found in C3 group where only 20% of study population was found normal and 10% was osteoporotic which clearly shows that MCI is good enough to assess the changes of bone mineral density

Table 4: In C3 group, normal population comprised of 16.5% of females and 25% males. Osteopenia in C3 group affected 66.7% females and 75% males while osteoporosis affected only 16.7% females in C3 group and none in males. Trend correlates with other similar studies, depicting increased frequency of female involvement.

Table 5 reveals absence of osteoporosis in both gender in c2 group. While 50% of females were normal , 50% had incidence of osteopenia. Among the males, 66.7% were normal and 33.3% had osteopenia. This is in concordance with other identical studies showing good correlation.

Table 6 clearly shows that according to MCI, C2 & C3 group were 67% and 20% normal respectively. Incidence of osteopenia was 33% in C2 group and 70% in C3 group where as Osteoporosis was present only among 10% of population in C3 group.

There is statistically significant correlation present between DEXA and MCI so MCI can also be used as an alternative to DEXA for measuring Bone mineral density.

Table 7 shows the cross tabulation between Dexa and OPG so

The total true positive cases are 24 (A)

Total True negative cases are 36 (D)

Total false positive cases are 16 (C)

Total false negative cases are 0 (B)

According to the above

Sensitivity = a/(a+b) = 100% (95% C I = 85.75%-100%)

Specificity = d /(c+d) = 69.23% (95% C I = 54.90%-81.28%)

Positive predictive value (PPV) = a/(a+c) = 60% (95% C I = 49.94% - 69.28%)

Negative predictive value (NPV) = d/(b+d) = 100%

Accuracy = (a+b)/(a+b+c+d) = 78.95% (95% CI = 60.08-87.46)

As the sensitivity is cent percent MCI can very well be used as screening tool for detecting changes in bone mineral density.

TABLES:

Table 1: Distribution of study population according to gender

Gender	C1		C2		C3	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Female	5	25.0	8	40.0	12	60.0
Male	15	75.0	12	60.0	8	40.0
Total	20	100.0	20	100.0	20	100.0

Table 2: Distribution according to dexa report in various groups

Dexa Report	C1		C2		C3	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Normal	20	100.0	12	60.0	4	20.0
Penia	0	0	8	40.0	14	70.0
Porosis	0	0	0.0	0.0	2	10.0
Total	20	100.0	20	100.0	20	100.0

Table 3: Distribution according to DEXA report in various groups according to gender (C3)

DEXA report	Female		Male	
	Frequency	Percentage	Frequency	Percentage
Normal	2	16.7	2	25.0
Penia	8	66.7	6	75.0
Porosis	2	16.7	0	0.0
Total	12	100.0	8	100.0

Table 4: Distribution according to DEXA report in various groups according to gender (C2)

DEXA report	Female		Male	
	Frequency	Percentage	Frequency	Percentage
Normal	4	50.0	8	66.7
Penia	4	50.0	4	33.3
Porosis	0	0	0	0
Total	8	100.0	12	100.0

Table 5: Comparison of MCI index with Dexa Report

Dexa	Mandibular Cortex Index			Total
	C1	C2	C3	
Normal	20 (100)	12 (66.7)	4 (20)	36 (60)
Penia	0	8 (33.3)	14 (70)	22 (36.6)
Porosis	0	0	2 (10)	2 (3.7)
Total	20 (100)	20 (100)	20 (100)	60 (100)
Chi sq	28.12		P value	<0.001**

** Highly significant (p<0.001)

Table 6: Sensitivity and specificity of MCI

DEXA * OPG Crosstabulation				
Count				
		OPG		Total
		Normal	Diseased	
DEXA	Normal	20	16	36
	Diseased	0	24	24
Total		20	40	60

CHARTS

Chart 1

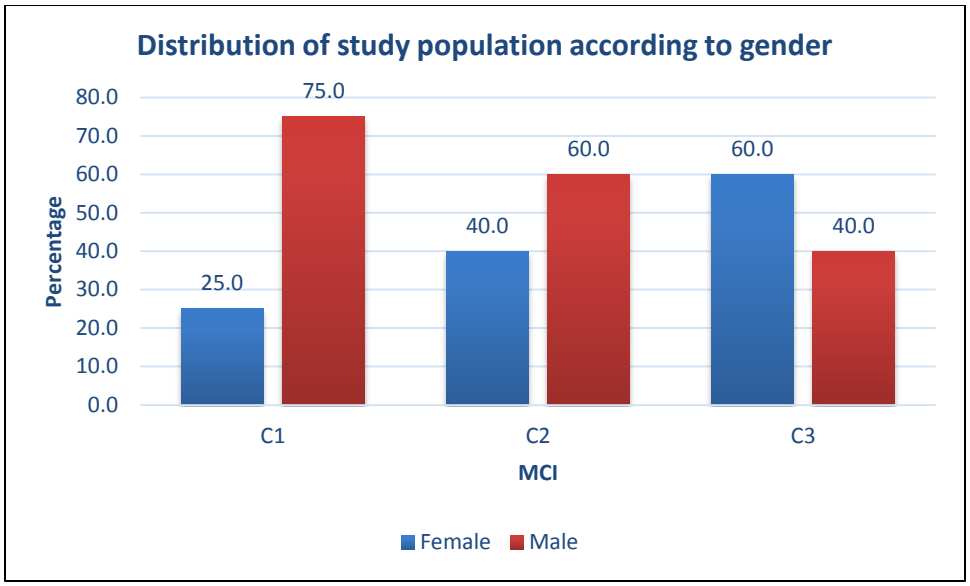


Chart 2

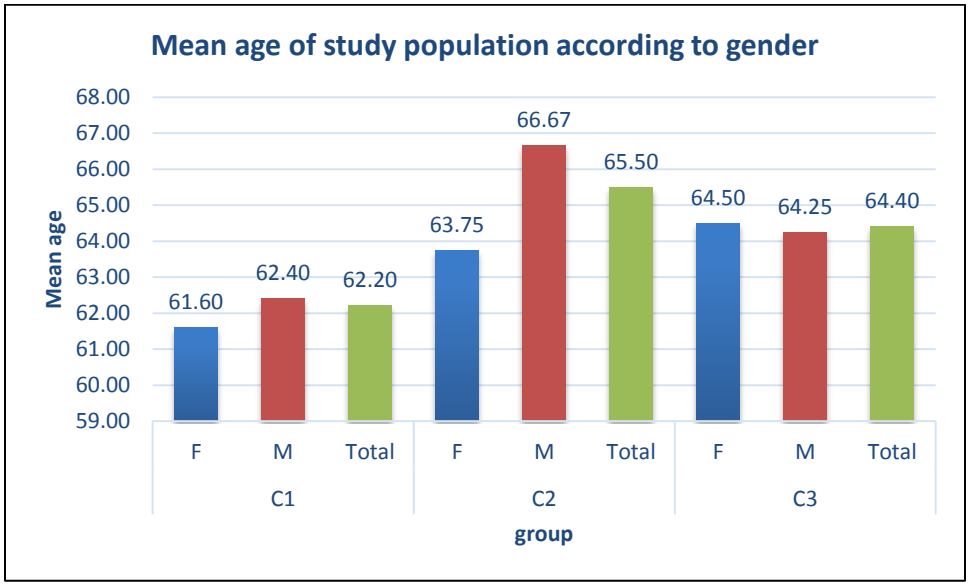


Chart 3

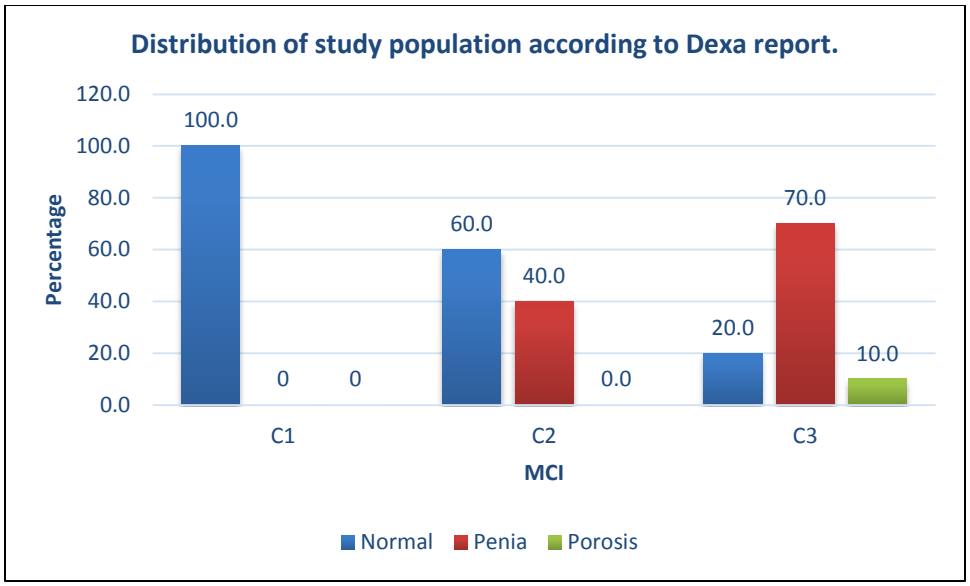


Chart 4

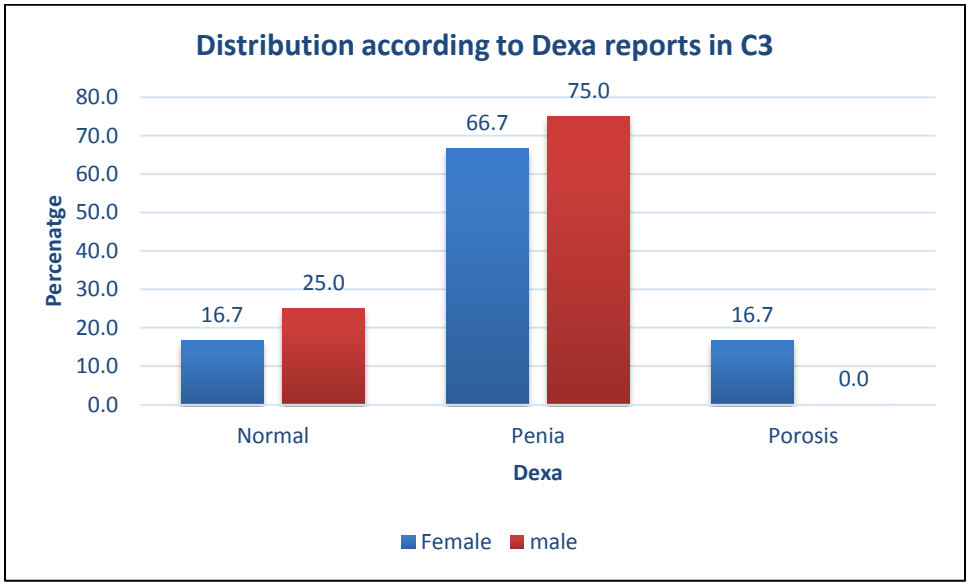


Chart 5

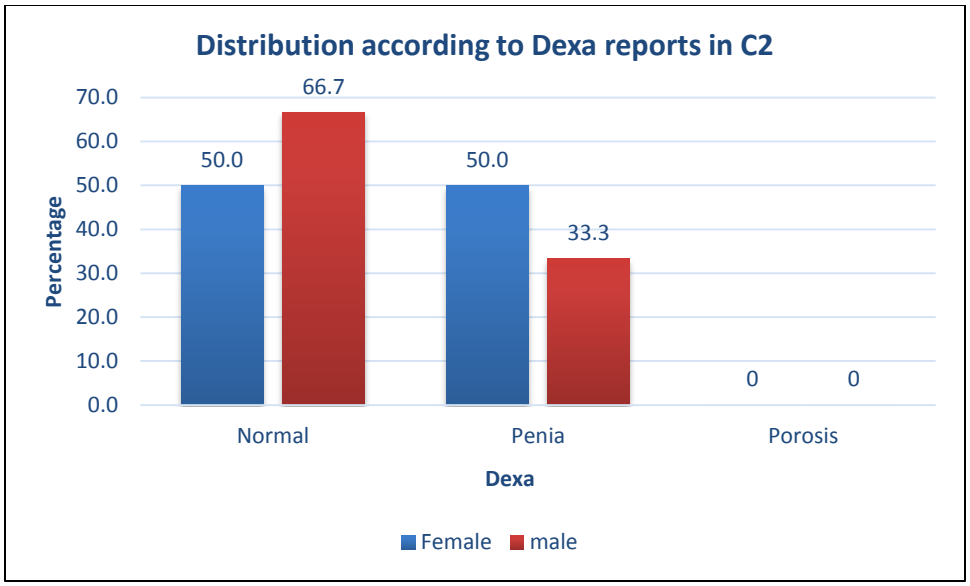
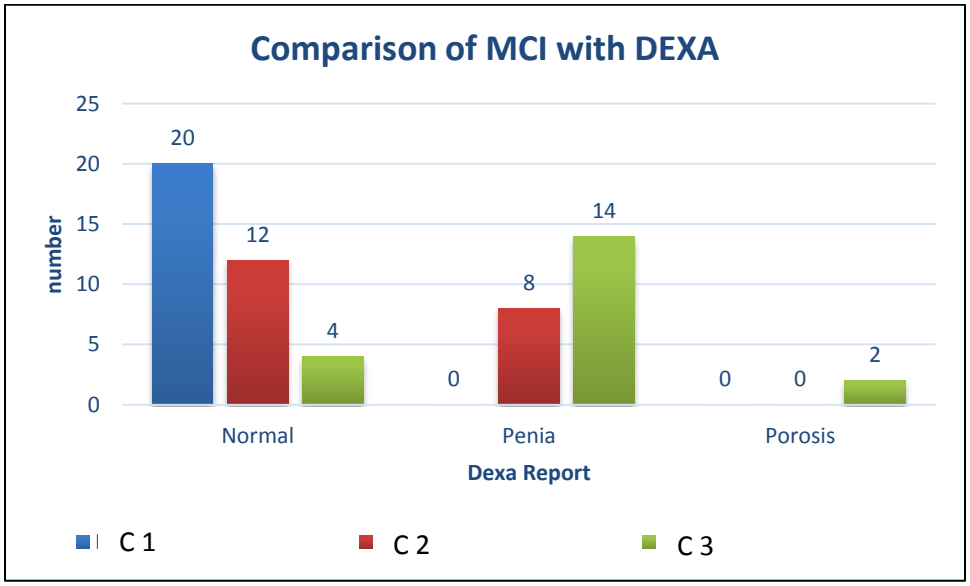


Chart 6



DISCUSSION

Osteoporosis is defined as a systemic skeletal disorder characterized by low bone mass and microarchitectural deterioration of the bone scaffold that results in increased bone fragility and susceptibility to fracture. Osteoporosis is the most common metabolic bone disease in the world, affecting more than 325 million individuals aged 65 years and older. Calcium is essential for proper functioning of the heart, brain, and other organs. To keep those critical organs functioning, the body reabsorbs calcium that is stored in the bones to maintain blood calcium levels. If calcium intake is not sufficient or if the body does not absorb enough calcium from the diet, bone production and bone tissue may suffer. Early screening and diagnosis of osteoporosis can save many lives[71].

According to World Health Organization T-score of -2.5 or below is defined as osteoporotic, T-score of -1.0 or greater is normal and T-score between -1.0 and -2.5 is osteopenia. The gold standard for determining osteoporosis is DEXA (Dual Energy X-ray Absorptiometry. The International Osteoporosis Foundation has recommended at least 10.6 DXA machines per million for detection of osteoporosis, but in many countries, the availability of DXA machines is far less than recommended. It is only 0.46 per million in China, 0.1 per million in Sri Lanka, 0.1 per million in Pakistan, 4.2 per million in Britain, 0.26 per million in India and so forth.

Indices using panoramic radiographs have been proposed as an indicator of the bone mineral density[72]. These indices can be of two types - radiomorphometric indices and densitometric indices. Radiomorphometric index is based on the morphological or visual analysis of the panoramic radiograph[73]. Densitometric analysis involves quantitative measurements and analysis. A number of mandibular indices based on panoramic radiographs, image processing,

and analysis techniques were developed to attempt quantification of mandibular bone mass and trabecular architecture description to discriminate individuals with and without osteoporosis. Klemetti et al had proposed a radiomorphometric index based on the visual appearance of the lower border of mandible. This was called as Mandibular cortical index (MCI).

In this study the correlation between panoramic radiograph parameters as defined by klemetti to discriminate the three variations in the cortex of mandible and osteoporosis as defined according to the WHO Guidelines using T- score of DEXA as the confirmatory diagnosis. The guidelines consider the BMD indeed as the only guiding parameter, as is the case in the WHO definition. Other factors such as age, maternal history of osteoporosis or fracture, personal history of fractures, cigarette smoking and multiple falls, as falls are one of main reasons for fractures were not considered. Panoramic radiograph is widely used for dental examination as it is convenient, fast, cost effective as compared to the other advanced imaging modalities and are more abundantly available and can effectively address the discrepancy between need and feed, so as to facilitate early detection and treatment of osteoporosis that would reduce associated morbidity and mortality.[74]

A correlation between systemic osteoporosis respectively reduced BMD and mandibular radiograph findings were examined and concluded in many publications[75-77]. Scientific sources indicate that by analyzing Cortical Bone (CB) of the mandible using panoramic radiographic images, it is possible to diagnose the total skeletal BMD reduction in up to 95% of cases. In panoramic radiographic images, the mandibular cortical index (MCI) according Klemetti could be identified and it shows the solidity of the mandibular cortical bone layer at the base and the morphological changes occurring in the development of Osteoporosis (OP)[81]. Some authors have reported that the index is useful for the screening of postmenopausal patients with osteoporosis

and is well correlated with skeletal bone loss. Other researchers discussed MCI efficacy and concluded that a large sample size was needed in order the index would be useful in BMD studies and that in other cases, it was not sufficiently precise for evaluation. Commonly in these studies, the patients first underwent a DEXA examination to determine the BMD and then standardised panoramic radiographs were made, often using one device. Based on this background the present study evaluated the relation between Mandibular cortical index and the bone mineral density of the lumbar spine and neck of femur. In contrast to other studies, this study was performed on patients, who came as outpatient to our Oral Medicine and Radiology department. This study was designed in this manner to simulate the daily routine in an outpatients practice, as it is usually the case in any Oral Medicine and Radiology hospital unit.

We chose a cross sectional trial design to increase the validity of the results in this study. In a controlled trial Law et al. examined the correlation between fractal dimension, microdensitometry, pixel intensity and panoramic analysis of cortical thickness on panoramic radiographs on the one hand, with diagnosed osteoporosis using radiographic evidence of vertebral compression fractures, medical histories, physical examinations and laboratory tests, also with data from QCT, SXA, DXA, SPA and DPA of the spine on the other hand[82]. A further controlled study was conducted by Bollen et al. examining the correlation between Cortical Index (CI) and the cortical thickness below the mental foramen and osteoporosis as defined by self reported osteoporotic fractures[83]. Bozic and Ihan Hren analysed the correlation between newly defined panoramic parameters and the presence of osteoporosis, diagnosed by DXA.

As the decrease in density and increase in porosity of human bones begins at about the third decade of life, the lower age limit in this study was set as the sixth decade[84]. Sixty geriatric men and women were included in this study with the age ranging from 60 and above. As there is a

high risk of osteoporosis associated with increasing age because of which the present study was done on geriatric subjects whose health status of at least one year as confirmed by detailed history[85]. In the present study 60% patients had normal bone mineral density and the rest 40% of patients had reduced bone mineral density. This is consistent with other studies that also showed the irrefutable evidence of higher incidence of osteoporosis associated with elderly patients.

The incidence of reduced bone density were higher among females in this study. This finding is in concordance with the trend found previously in other studies. Mundy postulated that rapid withdrawal of sex hormones (menopause in women) leads to faster bone loss compared to men who have a gradual decline in sex hormone production. Klemetti and Kolmakow reported a significant correlation between BMD and mandibular cortex morphology (MCI). Similar results were found in studies conducted by Horner and Devlin and Watanabe et al[86].

Based on the DEXA report, 2 (3.7%) patients had osteoporosis, 22 (36.6%) osteopenia and 36 (60%) patients had normal findings. Among this 3.7% of all included female patients had osteoporosis. In a similar Swedish statistic, based on the measured BMD with DXA, 7.8% of all included men had osteoporosis, while 51.5% of all included women had a T-score of less than -2.5 and consequently were categorized as having osteoporosis.

The validity of any indices, however, depends on their sensitivity and specificity as compared to the bone mineral densitometry results. In one of the study, the sensitivity and specificity values for MCI were 77% and 53% respectively. In other study the sensitivity and specificity were 100% and 88% respectively. The study of Drozdzowska et al[87]., showed a sensitivity and a specificity of 93% and 31 % respectively. Taguchi et al. evaluated the significance of the MCI in detecting osteoporotic postmenopausal women, the BMD was assessed using DXA on the

lumbar spine. A sensitivity of 86.8% and a specificity of 63.6% were found. The BMD-threshold for osteoporosis was set at a T-score of -2.5 and a correlation with the MCI categories severe and mild was examined. In a later study, Taguchi et al. included postmenopausal women, who were under 65 years in a study, when a sensitivity and a specificity of 72.6% and 74.0% respectively were concluded when the T-score threshold was set by -2.0. However, a sensitivity of 86.7% and a specificity of 65.6% were found at a T-score threshold of -2.5. In this study the BMD in this study was assessed at the lumbar spine and the femoral neck using DXA. Halling et al. evaluated the significance of the MCI in detecting a low BMD in 211 men and women older than 60 years as measured using DXA on both heels, a threshold was set at -1.5. The MCI categories normal and mild were correlated with a BMD, while a low BMD was correlated with the CI category severe. A sensitivity of 50% and a specificity of 89% were found[88]. Sutthiprapaporn et al. conducted a similar study in which the BMD was assessed using DXA on the lumbar spine and the proximal femur. The threshold for a reduced BMD was set at a T-score of -1.0. A sensitivity of 73.0% and a specificity of 49% were concluded. In this study geriatric population of both men and women were included, MCI was used as a diagnostic criteria and it was compared with gold standard i.e. DEXA results. Thus, sensitivity and specificity of MCI showed good results, with their values being 100% and 69% respectively were observed when the T-score threshold was set by -2.5 as defined by WHO.

As it is evident, one of the exceedingly frequent studied variable of mandibular bone related to osteoporosis is the integrity and homogeneity of the mandibular cortical bone. Accordingly in this study, MCI was a reliable index in identifying reduced BMD. ($P = 0.01$). The findings in this study reported both geriatric men and women with distinctly thinner and porous mandibular cortices presented with lower BMDs which were similar with the study done by Bras *et al.*[89] We

detected a comparably high prevalence of reasonably atrophied cortex on orthopantomograms (OPGs) of men and women aged above 65 years. This observation was in accordance with the research done by Ledgerton *et al.* and Uysal *et al.*[90] Zlatarić and Čelebić who proclaimed patients with diminished BMD values in the mandible, have a much greater atrophied and porous mandibular cortex. Contrast to other quantitative indices, MCI (qualitative index) does not need exact recognition of radiographic landmarks and accurate analysis. On the contrary, studies done by Jowitt *et al.*[91] and Drozdwaska *et al.* did not show an association between MCI and BMD condition. As MCI is an objective index, there could be several reasons attributed to the varied results.

Taguchi et al., in their study, suggested that it was possible that the crude threshold of cortical width for identifying low vertebral BMD or osteoporosis in Japanese post-menopausal women could not be used directly for British post-menopausal women, because of the difference in the sizes of their mandibles[92]. Also, no published data are available, which have prescribed the threshold values for the various mandibular indices, which can be used in the Indian population, as studies with larger sample sizes have not yet been conducted in India. Different sample sizes, different versions of dental panoramic equipment, image quality of an OPG, magnification variations, and presence of ghost images are a few of them to mention and 2 (3.7%) were osteoporotic. The proportional distribution of MCI categorization was C1, C2, and C3 with 20 in each group. The proportion of categorization was approximately equal, with narrow internal differences between BMD conditions and MCI categories, hence the difference between groups was statistically significant (P = 0.01). These results suggested that deteriorating cortical morphology showed a progressive link with osteopenia and osteoporosis.

Limitations of study:

However, there were certain limitations of the current study. Reduction in number and height of alveolar ridges could not be studied because of limited resources, data such as body size, prior fracture, other clinical risk factors for osteoporosis, rural or urban stay, number of absent teeth, education were not collected, and the hormonal levels were not included in the study and all participants were assumed to have normal estrogen levels. This being a well known fact that estrogen levels definitely effect the bone mass status, exclusion criteria of the study did not rule out abnormal hormonal levels. In addition to this, a bigger sample size could have allowed to conclude in prospect of prevalence of osteoporosis and as this was a preliminary study done in an geriatric Indian population; hence, multifactorial analysis and stepwise regression analysis were not done. The study still succeeds to show findings with respect to age in addition to low bone mass which could be looked forward by orthopedic community.

Finally, the MCI index validity is limited due to its poor reproducibility and significant intra- and inter-examiner variability. In addition, BMD of the spine, neck of femur was used to evaluate bone condition in this study. However, the skeleton is heterogenetic, and BMD differs in each area. When we evaluate the general bone condition, serum and urinary markers may also be appropriate. In the past, several investigations were conducted using mandibular inferior cortex (MIC) classification according to the method of Klemetti et al. to evaluate the jawbone. Radiographic findings are affected by many factors, i.e., difficulties in standardizing head position, X-ray projection, radiation dose, and anatomic variability of bony structures. However, it was reported that disagreement caused by positioning error and operator error for the MIC was negligible[268]. The MIC is a visible bony structure in the jawbone. Some investigators have reported satisfactory levels of reproducibility of the MIC classification[94].

SUMMARY AND CONCLUSION

As osteoporosis being a preventable and treatable disorder if detected early, diagnostic techniques are of major importance[94]. The dentist is often the most regularly visited doctor in the elderly population, and dental radiographs are the most frequently used imaging modality[95]. The panoramic radiograph is widely used for routine examinations and universally available.

Totally 60 cases were included under the study out of which 25 were female and 35 were male. The cases were selected from the Department of Oral Medicine and Radiology, Tamil Nadu Government Dental College and Hospital, Chennai – 600 003 between June 2016 and November 2017. All were in the age group of 60 years and above. The goal of the study was to establish changes in mandible so that a simple screening tool could be developed to advise geriatric population for further bone assessment. With sensitivity being more than 95% Mandibular Cortical Index can reliably be used as a diagnostic tool for screening patients with osteoporosis. These findings concluded that OPG X-rays could be used by orthopedic community to add this cost effective radiographic technique to their investigation list supporting financially compromised subjects of our community. As this screening method is uncomplicated, quick and performable without special instruments. Hence this method can be integrated into the daily routine of a referral practice or unit. This was simulated by our study design as we often deal with non-standardised panoramic radiographs. Finally, dental surgeons who use Orthopantomographs may play a vital role in screening patients with osteoporosis, mainly geriatric; this is because, it is most often advised as a part of routine investigation and as it is also less expensive than DEXA scan. Furthermore, special training of dental practitioners is advisable, concerning screening of osteoporosis in dental patients, as well as their further familiarization with digital x-ray practice. Finally, automated digital software for osteoporosis

screening could be included in the purchase of new panoramic x-ray machines, so that dental surgeons can help in the detection of osteoporosis.

By utilising the results of this study, undertaking further studies in this field may throw some light on patients with secondary osteoporosis and on geriatric patients with low bone mineral density in geriatric Indian population. The large number of dental radiographic examinations carried out each year raises the possibility that useful information concerning bone mineral status of patients remains untapped. For this reason, radiographic markers of osteoporosis in the mandible should be identified. In the absence of national screening program for osteoporosis, dental practitioners might identify those patients who appear to be at high risk by evaluation of dental radiographs.

MCI on digital OPG are an economical and reliable screening tool option to rule out osteoporosis or osteopenia in undiagnosed patients, which would save on the cost of a direct DXA examination. Furthermore, it would save needless referral of a patient to a distant center in case of absence of a nearby DXA facility, as is frequent in the less-developed nation as us, whereas OPGs are universally available. For dental surgeons, such investigations have a double-pronged advantage: In case osteoporosis or osteopenia is detected,

(1) Timely intervention can improve treatment prognosis

(2) Necessary modification of treatment plan can be performed.

Within the limitations of this study, it appears that using MCI on panoramic radiographs may be beneficial for assessment of osteoporosis. With sensitivity being more than 95% Mandibular

Mandibular Cortical Index can reliably be used as a diagnostic tool for screening patients with osteoporosis. It should be emphasized that diagnosis of osteoporosis can be safely assessed only by DXA examination and signs in the oral cavity and dental x-rays can only be used for primary screening. Dental surgeons contribution may be more important in areas with reduced DXA scanners availability and it is always necessary to take into account cost-effectiveness. Furthermore, dental surgeons should consider all aspects including medical history and risk factors of osteoporosis before further referring to an osteoporosis specialist for evaluation and possible DXA examination.

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TAMIL NADU GOVERNMENT DENTAL COLLEGE & HOSPITAL, CHENNAI – 3
TELEPHONE : 044-253403343
FAX: 044- 25300681

Ref No: R. C. NO: 0420/DE/2016 date : 28-07-2016
Sub: IEC review of the research proposals

Title of the work: Diagnostic validity of orthopantomograph compared to Dual Energy X-ray Absorptiometry scan in diagnosing osteoporosis in geriatric population- A comparative cross-sectional study.

Principal Investigator: Dr. D.Prasanna kumar
II year , MDS

Department : Department of Oral Medicine and Radiology
Tamil Nadu Govt. Dental College & Hospital , Chennai-3

Thank you for submitting your research proposal , which was considered at the Institutional Ethics Committee meeting held on the 1st. July 2016, at TN Govt. Dental College and the documents related to the study referred above were discussed and the modifications done as suggested and reported to us through your letter dated 20-07-2016 have been reviewed.

The decision of the members of the committee , the secretary and the Chairperson IEC of TN Govt. Dental College is here under:

Approved	Approved and advised to proceed with the study
Approved with suggestions	———
Revision	———
Rejected	———

The principal investigators and their team are advised to adhere to the guide lines given below:

1. You should get detailed informed consent from the patients / participants and maintain confidentiality.
2. You should carry out the work without affecting regular work and without extra expenditure to the Institution or the Government.
3. You should inform the IEC, in case of any change of study procedure, site, and investigating guide.
4. You should not deviate from the area of work for which you have applied for ethical clearance.
5. You should inform the IEC immediately in case of any adverse events or serious adverse reactions. You should abide to the rules and regulations of the institution(s) .
6. You should complete the work within specific period and if any extension of time is required, you should apply for permission again to do the work.
7. You should submit the summary of the work to the ethical committee every 3 months and on completion of the work.
8. You should not claim any kind of funds from the institution for doing the work or on completion/ or for any kind of compensations.
9. The members of the IEC have the right to monitor the work without prior intimation.
10. Your work should be carried out under the direct supervision of the guide/ Professor.

MEMBER SECRETARY,
INSTITUTIONAL ETHICS COMMITTEE
Tamil Nadu Govt. Dental College & Hospital
Chennai

CHAIRPERSON
INSTITUTIONAL ETHICS COMMITTEE
Tamil Nadu Govt. Dental College & Hospital
Chennai

PATIENT INFORMATION SHEET

Title of the study: "Diagnostic validity of orthopantomograph compared to DEXA scan in screening osteoporosis in geriatric population- a comparative study".

Name of research institution - Tamilnadu Government Dental College & Hospital, Chennai-03

Purpose of the study:
The aim of this study were to review the role of panoramic radiograph in routine dental treatment for an initial evaluation of osteoporosis and to discuss the reliability and accuracy of reported panoramic indices.

Procedures:
Patient selection followed by obtaining thorough history and informed consent. Complete Clinical Examination (intra and extra oral examination) by using diagnostic instrument set. Reduced bone density suspected with OPG followed by DEXA Scan examination and Confirmed

Risk of participation and protection:
Risk of Radiation exposure
Protection: Standard guidelines for radiation protection will be followed.

Benefits:
Patient will be benefited by more accurate evaluation osteoporosis followed by appropriate treatment.

Confidentiality
The identity of the patients participating in the research will be kept confidential throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Participant's rights
Taking part in the study is voluntary. You are free to decide whether to participate in the study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Compensation: Nil

Contact For queries related to the study: Dr.D. Prasanna kumar
Department of Oral Medicine and Radiology
Tamilnadu Govt. Dental College and Hospita
Chennai – 600003
Phone Number: 9566093099

(For queries related to the rights as a study participant, please write to: The Chairman, The Ethical Committee, Tamilnadu Government Dental College & Hospital, Chennai – 600003)

ஆராய்ச்சி பற்றிய தகவல் படிவம்

முதியோர் மக்கள் தொகை ஆஸ்டியோபோரோசிஸ் கண்டறிவதற்கு DEXA ஸ்கேன் ஒப்பிடும்போது OPG ஆகியவற்றிற்கும் கண்டறிவது செல்லுபடியாகும்

இந்த ஆராய்ச்சி செய்யும்பொருட்டு தமிழ்நாடு அரசு பல் மருத்துவமனை மற்றும் மருத்துவக் கல்லூரிக்கு வரும் நோயாளிகள் தேர்வு செய்யப்படுகிறார்கள்.

முதியோர் மக்கள் தொகை ஆஸ்டியோபோரோசிஸ் கண்டறிவதற்கு கலந்தாய்வு

நோயாளி பற்றிய குறிப்புகள் பிறர் அறியா வண்ணம் ஆராய்ச்சி முடியும்வரை இரகசியமாக பாதுகாக்கப்படும். அதை வெளியிடும் நேரத்தில் எந்த நோயாளியின் தனி அடையாளங்களும் வெளியிட வாய்ப்பு கிடையாது.

இந்த ஆராய்ச்சியில் பங்குபெறுவது நோயாளியின் தனிப்பட்ட முடிவு மற்றும் நோயாளிகள் இந்த ஆராய்ச்சியில் இருந்து எப்பொழுது வேண்டுமானாலும் விலகிக்கொள்ளலாம். நோயாளியின் இந்த முடிவு அவருக்கோ அல்லது ஆராய்ச்சியாளருக்கோ எந்தவித பாதிப்பும் ஏற்படாது என்பதை தெரியப்படுத்துகிறோம்.

இந்த ஆராய்ச்சியில் முடிவுகள் நோயாளிகளுக்கு ஆராய்ச்சி முடியும் தருவாயிலோ அல்லது இடையிலோ தெரிவிக்கப்படும். ஆராய்ச்சியின்பொழுது ஏதும் பின்விளைவுகள் ஏற்பட்டால் அதை சரிசெய்ய தகுந்த உதவிகள் அல்லது தேவையான சிகிச்சைகள் உடனடியாக மேற்கொள்ளப்படும்.

நோயாளியின் பெயர் கையொப்பம்/ கைரேகை

முதன்மை ஆய்வாளர்
தமிழ்நாடு அரசு பல் மருத்துவக் கல்லூரி,
சென்னை-600 003.

INFORMED CONSENT FORM

Study title "**Diagnostic validity of orthopantomograph compared to DEXA scan in screening osteoporosis in geriatric population- a comparative study**"

Participant ID No:

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care."

Date	Name of the participant	Signature/thumb impression of the participant

[The literate witness selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team; If the participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). This should be documented by the study staff by getting signature from the prospective participant]

"I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely"

Date	Name of the witness	Signature of the witness

Date	Name of the interviewer	Signature of the interviewer

ஆராய்ச்சி ஒப்புதல் படிவம்

முதியோர் மக்கள் தொகை ஆஸ்டியோபோரோசிஸ் கண்டறிவதற்கு DEXA ஸ்கேன் ஒப்பிடும்போது OPG ஆகியவற்றிற்கும் கண்டறிவது செல்லுபடியாகும்

பெயர் : வயது/பால்:

ஆராய்ச்சி சேர்க்கை எண்: புறநோயாளியின் எண்:

நான் என் சுய நினைவுடன் மற்றும் முழு சுதந்திரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் சேர்ந்துகொள்ள ஒப்புதல் அளிக்கிறேன். கீழ் காணப்படும் நிபந்தனைகளுக்கு ஒப்புதல் அளிக்கிறேன். இந்த ஆராய்ச்சியின் நோக்கமும் அதன் சிகிச்சை முறைகளும் எனக்கு திருப்தி அளிக்கும் வகையில் அறிவுறுத்தப்பட்டது.

நான் மருத்துவ சிகிச்சை முரைக்கு முழுமையாக ஒத்துழைத்து ஏதேனும் அசாதாரண நோய் அறிகுறிகள் ஏற்பட்டால் உடனடியாக என் மருத்துவருக்கு தெரிவிக்க ஒப்புக்கொள்கிறேன்.

என் மருத்துவ குறிப்பேடுகளை மருத்துவ ஆராய்ச்சியில் பயன்படுத்தசம்மதிக்கிறேன். இந்த ஆராய்ச்சி மையமும், ஆராய்ச்சியாளரும் என் அடையாளத்தை ரகசியமாக வைத்திருப்பதாக அறிகிறேன்.

நோயாளியின் பெயர் கையொப்பம் தேதி

ஆராய்ச்சியாளர் பெயர் கையொப்பம் தேதி

CASE PROFORMA

Diagnostic validity of orthopantomograph compared to DEXA scan in screening osteoporosis in geriatric population

Date: Serial no:

Name: O.P No:

Age/Sex:

Address:

Phone no:

Occupation: Income:

Religion:

Centre: Department of Oral Medicine And Radiology,

Tamil Nadu Govt Dental College & Hospital, Chennai -3

Presenting complaint with duration:

Past medical and surgical history:

Past dental history:

Personal history:

A) Diet:

B) Teeth cleansing habits:

- Cleaning aids used:
- Frequency :

C) Smoking habit:

Material used:

Frequency :

Duration of the habit:

D) Chewing habit:

Material used:

Frequency :

Duration of the habit:

E) Other habits (alcohol, snuff):

Marital status:

Family history:

Clinical examination

General examination

Extraoral Examination:

Facial Symmetry

Swelling

Lymph node examination

TMJ Examination

Intraoral examination:

Teeth**:**

Decayed

Mobility

Missing

Filled teeth

Gingiva

Labial and buccal mucosa:

Hard palate:

Soft Palate:

Pillar of fauces and Tonsils:

Tongue:

Floor of the mouth:

Retromolar trigone:

Investigations:

1. Biochemical / Haematological Investigation :
2. Others :

OPG Evaluation

Provisional Diagnosis

DEXA Evaluation

NAME OF THE INVESTIGATOR:

SIGNATURE OF THE INVESTIGATOR:

TRIPARTITE AGREEMENT

This agreement herein after the "Agreement" is entered into on this day ……. between the Tamil Nadu Government Dental College and Hospital represented by its Principal having address at Tamil Nadu Government Dental College and Hospital, Chennai- 600 003 , (hereinafter referred to as, 'the college')

And

Dr. S. JAYACHANDRAN, M.D.S., PhD., aged 54 years working as Professor in Department of Oral medicine and Radiology at the college, having residence address at A.M -16, TNHB quarters, Tod Hunter Nagar, Saidapet, Chennai – 15. (herein after referred to as the 'Principal Investigator')

And

Dr. D. PRASANNA KUMAR, aged 29 years currently studying as final year Post graduate student in the Department of Oral Medicine and Radiology, Tamil Nadu Government Dental College and Hospital, Chennai -3 (hereafter referred to as the 'PG and co- investigator') residing at 1st street thendral colony, annanagar west.ext Chennai- 600101.

Whereas the 'PG student' as part of his curriculum undertakes to research on "**Diagnostic validity of orthopantomograph compared to DEXA scan in screening osteoporosis in geriatric population- a comparative study**" for which purpose the Principal investigator shall act as Principal investigator and the College shall provide the requisite infrastructure based on availability and also provide facility to the PG student as to the extent possible as a Co-investigator

Whereas the parties, by this agreement have mutually agreed to the various issues including in particular the copyright and confidentiality issues that arise in this regard

Now this agreement witnessed as follows:

1. The parties agree that all the Research material and ownership therein shall become the vested right of the college, including in particular all the copyright in the literature including the study, research and all other related papers.
2. To the extent that the college has legal right to do go, shall grant to license or assign the copyright so vested with it for medical and/or commercial usage of interested persons/entities subject to a reasonable terms/conditions including royalty as deemed by the college.
3. The Royalty so received by the college shall be shared equally by all the three parties.
4. The PG/Research student and PG/Principal Investigator shall under no circumstances deal with the copyright, Confidential information and know how-generated during the course of research/study in any manner whatsoever, while shall sole west with the college.
5. The PG student and Principal Investigator undertake not to divulge (or) cause to be divulged any of the confidential information or, know-how to anyone in any manner whatsoever and for any purpose without the express written consent of the college.

6. All expenses pertaining to the research shall be decided upon by the principal investigator/Co-investigator or borne sole by the PG student.(co-investigator)
7. The college shall provide all infrastructure and access facilities within and in other institutes to the extent possible. This includes patient interactions, introductory letters, recommendation letters and such other acts required in this regard.
8. The Principal Investigator shall suitably guide the Student Research right from selection of the Research Topic and Area till its completion. However the selection and conduct of research, topic and area research by the Student Researcher under guidance from the Principal Investigator shall be subject to the prior approval, recommendations and comments of the Ethical Committee of the College constituted for this purpose.
9. It is agreed that as regards other aspects not covered under this agreement, but which pertain to the research undertaken by the PG student, under guidance from the Principal Investigator, the decision of the College shall be binding and final.
10. If any dispute arises as to the matters related or connected to this agreement herein, it shall be referred to arbitration in accordance with the provisions of the Arbitration and Conciliation Act, 1996.

In witness where of the parties herein above mentioned have on this the day month and year herein above mentioned set their hands to this agreement in the presence of the following two witnesses.

College represented by its Principal PG Student

Witnesses Student Guide

1.

2.

C3 MASTER CHART						
S.no	**Age**	**Sex**	**DEXA report**			
			Lumbar	**Lt hip**	**Rt hip**	**Final report**
1.	64	M	Normal	Normal	Normal	Normal
2.	60	F	Normal	Penia	Penia	Penia
3.	70	F	Porosis	Penia	Penia	Penia
4.	60	M	Penia	Penia	Penia	Penia
5.	63	F	Normal	Porosis	Normal	Normal
6.	65	M	Normal	Porosis	Normal	Normal
7.	64	M	Normal	Penia	Penia	Penia
8.	65	F	Penia	Penia	Penia	Penia
9.	65	F	Porosis	Penia	Penia	Penia
10.	63	F	Penia	Normal	Penia	Penia
11.	64	M	Normal	Penia	Penia	Penia
12.	70	M	Penia	Porosis	Penia	Penia
13.	60	F	Porosis	Penia	Penia	Penia
14.	65	F	Normal	Penia	Penia	Penia
15.	65	F	Penia	Normal	Normal	Normal
16.	64	F	Porosis	Penia	Penia	Penia
17.	65	F	Porosis	Porosis	Porosis	Porosis
18.	67	M	Penia	Penia	Penia	Penia
19.	69	F	Penia	Porosis	Porosis	Porosis
20.	60	M	Porosis	Penia	Penia	Penia

C2 MASTER CHART

S.no	Age	Sex	DEXA report			
			Lumbar	Lt hip	Rt hip	
1.	69	M	Normal	Normal	Normal	Normal
2.	66	M	Penia	Normal	Penia	Penia
3.	68	F	Penia	Penia	Penia	Penia
4.	60	M	penia	Penia	Porosis	Penia
5.	65	F	Penia	Normal	Normal	Normal
6.	75	M	Penia	Penia	Normal	Penia
7.	69	M	Normal	Normal	Normal	Normal
8.	71	M	Normal	Normal	Normal	Normal
9.	66	M	Penia	Penia	Penia	Penia
10.	60	M	Normal	Normal	Normal	Normal
11.	63	M	Normal	Penia	Normal	Normal
12.	60	M	Normal	Normal	Normal	Normal
13.	61	F	Penia	Normal	Normal	Normal
14.	67	F	Penia	Penia	Penia	Penia
15.	61	F	Normal	Penia	Normal	Normal
16.	69	M	Normal	Penia	Penia	Normal
17.	72	M	Normal	Normal	Normal	Normal
18.	66	F	Penia	Penia	Penia	Penia
19.	60	F	Normal	Normal	Normal	Normal
20.	62	F	Normal	Penia	Penia	Penia

Control Group C1			
No.	Age	Gender	Diagnosis
1.	63	M	Normal
2.	60	M	Normal
3.	61	F	Normal
4.	62	F	Normal
5.	64	M	Normal
6.	60	M	Normal
7.	65	M	Normal
8.	62	M	Normal
9.	63	M	Normal
10.	63	M	Normal
11.	61	F	Normal
12.	60	M	Normal
13.	63	M	Normal
14.	62	M	Normal
15.	65	M	Normal
16.	62	F	Normal
17.	61	M	Normal
18.	60	M	Normal
19.	65	M	Normal
20.	62	F	Normal